

What is claimed is:

- ~~1. An isolated outer membrane protein of *N. gonorrhoeae* having an apparent molecular weight of 85kDa and comprising an amino acid sequence selected from the group consisting of:
  - ~~(a) SEQ ID NO: 2~~
  - ~~(b) a fragment of (a);~~
  - ~~(c) an analog of (a) or (b) characterized by having at least 80% homology with SEQ ID NO: 2; and~~
  - ~~(d) a homolog of (a) or (b) characterized by having at least 80% homology with SEQ ID NO: 2.~~~~
- ~~2. The protein according to claim 1 which is a recombinant protein.~~
- ~~3. The protein according to claim 1 which is a synthetic protein.~~
- ~~4. The protein according to claim 1 which is fused to a second polypeptide or protein.~~
- ~~5. A nucleic acid sequence encoding the Omp85 of *N. gonorrhoeae* or a fragment thereof.~~
- ~~6. The nucleic acid sequence according to claim 5, selected from the group consisting of:
  - ~~(a) SEQ ID NO: 1~~
  - ~~(b) a sequence which hybridizes to (a) under stringent conditions;~~
  - ~~(c) an allelic variant of any of (a) and (b);~~
  - ~~(d) a fragment of any of (a) through (c); and~~
  - ~~(e) a mutant of (a) through (d).~~~~

- ~~7. The nucleic acid sequence according to claim 6 which employs preference codons for expression in a selected host cell.~~
- ~~8. A nucleic acid molecule comprising a nucleic acid sequence encoding the Omp85 of *N. gonorrhoeae* or a fragment thereof under the control of suitable regulatory sequences which direct expression of said Omp 85 or fragment in a selected host cell.~~
- ~~9. The molecule according to claim 8 which is a plasmid.~~
- ~~10. A host cell transformed with the molecule according to claim 8.~~
- ~~11. A recombinant virus comprising the molecule of claim 8.~~
- ~~12. A method of recombinantly expressing the Omp85 of *N. gonorrhoeae* or a fragment thereof comprising the steps of culturing a host cell of claim 10 under conditions which permit expression of said protein or peptide.~~
- ~~13. The method according to claim 12 further comprising the step of isolating said expressed protein from said cell or said cell medium.~~
- ~~14. The method according to claim 12 wherein said Omp85 protein is a fusion protein.~~
- ~~15. The method according to claim 12 wherein said Omp85 protein is a mutant protein.~~
- ~~16. A method for preparing an Omp85 protein of *N. gonorrhoeae* or fragment thereof comprising chemically synthesizing said protein or fragment.~~

~~17. A diagnostic reagent comprising a nucleic acid sequence selected from the group consisting of:~~

~~(a) a nucleic acid sequence encoding Omp85 of *N. gonorrhoeae*, isolated from cellular materials with which it is naturally associated;~~

~~(b) SEQ ID NO:1 or a sequence complementary thereto;~~

~~(c) a fragment of any of (a) or (b) comprising at least 15 nucleotides in length;~~

~~(d) a sequence which hybridizes to (a) through (c) under stringent conditions;~~

~~(e) an allelic variant of any of (a) through (d);~~

~~(f) a mutant of (a) through (e);~~

~~(g) a sequence encoding Omp85 or a fragment thereof fused to a sequence encoding a second protein;~~

~~and a detectable label which is associated with said sequence.~~

~~18. An isolated antibody which binds Omp85 of *N. gonorrhoeae* or a fragment thereof.~~

~~19. The antibody according to claim 18, which is specific for Omp85 of *N. gonorrhoeae* or a fragment thereof.~~

~~20. The antibody according to claim 18 produced by administering to a vertebrate host an Omp85 protein of *N. gonorrhoeae* or fragment thereof.~~

~~21. The antibody according to claim 18, isolated by immunizing said host with the protein of claim 1.~~

~~22. The antibody according to claim 18 which is selected from the group consisting of a chimeric antibody, a humanized antibody, a monoclonal antibody and a polyclonal antibody.~~

- ~~23. An anti-idiotypic antibody specific for the antibody of claim 18.~~
- ~~24. A diagnostic reagent comprising the antibody according to claim 18 and a detectable label.~~
- ~~25. A vaccine composition comprising an effective amount of a Omp85 protein of *N. gonorrhoeae*, a fusion protein or fragment thereof and a pharmaceutically acceptable carrier.~~
- ~~26. The composition according to claim 25 which is a polyvalent vaccine further comprising at least one other antigen or fragment thereof from a heterologous pathogenic species or a homologous pathogenic species.~~
- ~~27. The composition according to claim 25 wherein said Omp85 protein or fragment and said other antigen are in the form of a fusion protein.~~
- ~~28. A vaccine composition comprising an effective amount of a nucleic acid sequence encoding the Omp85 protein of *N. gonorrhoeae*, a fusion protein, or a fragment thereof and a suitable nucleic acid delivery vehicle.~~
- ~~29. The composition according to claim 28 which is a polyvalent vaccine further comprising at least one other nucleic acid sequence encoding an antigen or fragment thereof from a heterologous pathogenic species or a homologous pathogenic species.~~
- ~~30. The composition according to claim 29 wherein said nucleic acid sequence encodes said Omp85 protein or fragment and said other antigen in the form of a fusion protein~~

~~31. A method of vaccinating a human or animal against non-symptomatic gonococcal infection or symptomatic disease comprising administering to said human or animal a composition comprising an effective amount of the composition of claim 25.~~

~~32. A method of vaccinating a human or animal against non-symptomatic gonococcal infection or symptomatic disease comprising administering to said human or animal a composition comprising an effective amount of the composition of claim 28.~~

~~33. A method for diagnosing non-symptomatic gonococcal infection or symptomatic disease in a human or animal comprising the steps of:~~  
~~contacting an Omp85 antigen optionally associated with a detectable label or a homolog thereof with a biological sample from a human subject to be diagnosed, wherein the presence of naturally occurring antibodies to *N. gonorrhoeae* in said sample permits the formation of an antigen-antibody complex, and~~  
~~analyzing said sample for the presence of said complex, which indicates infection with *N. gonorrhoeae*.~~

~~34. A method for diagnosing non-symptomatic gonococcal infection or symptomatic disease in a human or animal comprising the steps of:~~  
~~contacting an Omp85 antibody, optionally associated with a detectable label, with a biological sample from a human subject to be diagnosed, wherein the presence of naturally occurring *N. gonorrhoeae* Omp85 in said sample permits the formation of an antigen-antibody complex, and~~  
~~analyzing said sample for the presence of said complex, which indicates infection with *N. gonorrhoeae*.~~

~~35. A method for diagnosing non-symptomatic gonococcal infection or symptomatic disease in a human or animal comprising the steps of:~~

~~employing a nucleic acid sequence encoding all or a portion of an Omp85 antigen or an Opm85 antibody, optionally associated with a detectable label, as a probe which, when in contact with a biological sample from a human subject to be diagnosed, enables detection of infection by hybridization or amplification of nucleic acid sequences of *N. gonorrhoeae* Omp85 in said sample.~~

~~36. A therapeutic composition useful in treating humans or animals with non-symptomatic gonococcal infection or symptomatic disease comprising at least one anti-Omp85 antibody and a suitable pharmaceutical carrier.~~

~~37. A method for treating non-symptomatic gonococcal infection or symptomatic disease in a mammalian host comprising administering an effective amount of a composition according to claim 36.~~

~~38. A kit for diagnosing infection with *N. gonorrhoeae* in a human or animal comprising a component selected from the group consisting of an Omp85 protein of *N. gonorrhoeae*, a fragment thereof, an anti-Omp85 antibody of claim 16, a nucleic acid sequence encoding an Omp85 protein of *N. gonorrhoeae*, and a fragment thereof, and suitable detectable labels.~~

~~39. A method of identifying compounds which specifically bind to Omp85 of *N. gonorrhoeae* or a fragment thereof, comprising the steps of contacting said Omp85 protein or fragment thereof with a test compound to permit binding of the test compound to Omp85, and determining the amount of test compound which is bound to Omp85.~~

~~40. A compound identified by the method of claim 39.~~

~~41. An isolated outer membrane protein of *N. meningitidis* having an apparent molecular weight of 85kDa and comprising an amino acid sequence selected from the group consisting of:~~

- ~~(a) SEQ ID NO: 4~~
- ~~(b) a fragment of (a);~~
- ~~(c) an analog of (a) or (b) characterized by having at least 80% homology with SEQ ID NO: 4; and~~
- ~~(d) a homolog of (a) or (b) characterized by having at least 80% homology with SEQ ID NO: 4.~~

~~42. The protein according to claim 41 which is a recombinant protein.~~

~~43. The protein according to claim 41 which is a synthetic protein.~~

~~44. The protein according to claim 41 which is fused to a second polypeptide or protein.~~

~~45. A nucleic acid sequence encoding the Omp85 of *N. meningitidis* or a fragment thereof.~~

~~46. The nucleic acid sequence according to claim 45, selected from the group consisting of:~~

- ~~(a) SEQ ID NO: 3~~
- ~~(b) a sequence which hybridizes to (a) under stringent conditions;~~
- ~~(c) an allelic variant of any of (a) and (b);~~
- ~~(d) a fragment of any of (a) through (c); and~~
- ~~(e) a mutant of (a) through (d).~~

~~47. The nucleic acid sequence according to claim 45 which employs preference codons for expression in a selected host cell.~~

~~48. A nucleic acid molecule comprising a nucleic acid sequence encoding the Omp85 of *N. meningitidis* or a fragment thereof under the control of suitable regulatory sequences which direct expression of said Omp 85 or fragment in a selected host cell.~~

~~49. The molecule according to claim 48, which is a plasmid.~~

~~50. A host cell transformed with the molecule of claim 48.~~

~~51. A recombinant virus comprising the molecule of claim 48.~~

~~52. A method of recombinantly expressing the Omp85 of *N. meningitidis* or a fragment thereof comprising the steps of culturing a recombinant host cell transformed with a nucleic acid sequence encoding said protein or fragment under conditions which permit expression of said protein or peptide.~~

~~53. The method according to claim 52 further comprising the step of isolating said expressed protein from said cell or said cell medium.~~

~~54. The method according to claim 52 wherein said Omp85 protein is a fusion protein.~~

~~55. The method according to claim 52 wherein said Omp85 protein is a mutant protein.~~

~~56. A method for preparing an Omp85 protein of *N. meningitidis* or fragment thereof comprising chemically synthesizing said protein or fragment.~~



~~57. A diagnostic reagent comprising a nucleic acid sequence selected from the group consisting of:~~

- ~~(a) a nucleic acid sequence encoding Omp85 of *N. meningitidis*, isolated from cellular materials with which it is naturally associated;~~
- ~~(b) SEQ ID NO.3 or a sequence complementary thereto;~~
- ~~(c) a fragment of any of (a) or (b) comprising at least 15 nucleotides in length;~~
- ~~(d) a sequence which hybridizes to (a) through (c) under stringent conditions;~~
- ~~(e) an allelic variant of any of (a) through (d);~~
- ~~(f) a mutant of (a) through (e);~~
- ~~(g) a sequence encoding Omp85 or a fragment thereof fused to a sequence encoding a second protein;~~
- ~~and a detectable label which is associated with said sequence.~~

~~58. An isolated antibody which binds Omp85 of *N. meningitidis* or a fragment thereof.~~

~~59. The antibody according to claim 58 which is specific for Omp85 of *N. meningitidis* or a fragment thereof.~~

~~60. The antibody according to claim 58 produced by administering to a vertebrate host an Omp85 protein of *N. meningitidis* or fragment thereof.~~

~~61. The antibody according to claim 58, isolated by immunizing said host with the protein of claim 41.~~

~~62. The antibody according to claim 58 which is selected from the group consisting of a chimeric antibody, a humanized antibody, a monoclonal antibody and a polyclonal antibody.~~

- ~~63. An anti-idiotypic antibody specific for the antibody of claim 58.~~
- ~~64. A diagnostic reagent comprising the antibody according to claim 58 and a detectable label.~~
- ~~65. A vaccine composition comprising an effective amount of a Omp85 protein of *N. meningitidis*, a fusion protein or fragment thereof and a pharmaceutically acceptable carrier.~~
- ~~66. The composition according to claim 65 which is a polyvalent vaccine further comprising at least one other antigen or fragment thereof from a heterologous pathogenic species or a homologous pathogenic species.~~
- ~~67. The composition according to claim 65 wherein said Omp85 protein or fragment and said other antigen are in the form of a fusion protein.~~
- ~~68. A vaccine composition comprising an effective amount of a nucleic acid sequence encoding the Omp85 protein of *N. meningitidis*, a fusion protein, or a fragment thereof and a suitable nucleic acid delivery vehicle.~~
- ~~69. The composition according to claim 68 which is a polyvalent vaccine further comprising at least one other nucleic acid sequence encoding an antigen or fragment thereof from a heterologous pathogenic species or a homologous pathogenic species.~~
- ~~70. The composition according to claim 68 wherein said nucleic acid sequence encodes said Omp85 protein or fragment and said other antigen in the form of a fusion protein~~

~~71. A method of vaccinating a human or animal against non-symptomatic meningococcal infection and symptomatic disease comprising administering to said human or animal a composition comprising an effective amount of the composition of claim 68.~~

~~72. A method of vaccinating a human or animal against non-symptomatic meningococcal infection and symptomatic disease comprising administering to said human or animal a composition comprising an effective amount of the composition of claim 68.~~

~~73. A method for diagnosing non-symptomatic meningococcal infection and symptomatic disease in a human or animal comprising the steps of:~~  
~~contacting an Omp85 antigen optionally associated with a detectable label or a homolog thereof with a biological sample from a human subject to be diagnosed, wherein the presence of naturally occurring antibodies to *N. meningitidis* in said sample permits the formation of an antigen-antibody complex, and~~  
~~analyzing said sample for the presence of said complex, which indicates infection with *N. meningitidis*.~~

~~74. A method for diagnosing non-symptomatic meningococcal infection and symptomatic disease in a human or animal comprising the steps of:~~  
~~contacting an Omp85 antibody, optionally associated with a detectable label, with a biological sample from a human subject to be diagnosed, wherein the presence of naturally occurring *N. meningitidis* Omp85 in said sample permits the formation of an antigen-antibody complex, and~~  
~~analyzing said sample for the presence of said complex, which indicates infection with *N.*~~

~~73. A method for diagnosing non-symptomatic meningococcal infection and symptomatic disease in a human or animal comprising the steps of~~  
~~contacting an Omp85 antigen optionally associated with a detectable label or a homolog thereof with a biological sample from a human subject to be diagnosed;~~  
~~wherein the presence of naturally occurring antibodies to *N. meningitidis* in said sample permits the formation of an antigen-antibody complex, and~~  
~~analyzing said sample for the presence of said complex, which indicates infection with *N. meningitidis*.~~

~~74. A method for diagnosing non-symptomatic meningococcal infection and symptomatic disease in a human or animal comprising the steps of:~~  
~~contacting an Omp85 antibody, optionally associated with a detectable label, with a biological sample from a human subject to be diagnosed, wherein the presence of naturally occurring *N. meningitidis* Omp85 in said sample permits the formation of an antigen-antibody complex, and~~  
~~analyzing said sample for the presence of said complex, which indicates infection with *N. meningitidis*.~~

~~75. A method for diagnosing non-symptomatic meningococcal infection and symptomatic disease in a human or animal comprising the steps of:~~  
~~employing a nucleic acid sequence encoding all or a portion of an Omp85 antigen or an Omp85 antibody, optionally associated with a detectable label, as a probe which, when in contact with a biological sample from a human subject to be diagnosed, enables detection of infection by hybridization or amplification of nucleic acid sequences of *N. meningitidis* Omp85 in said sample.~~

~~76. A therapeutic composition useful in treating humans or animals with non-symptomatic meningococcal infection and symptomatic disease comprising at least one anti-*N. meningitidis* Omp85 antibody and a suitable pharmaceutical carrier.~~

~~77. A method for treating non-symptomatic meningococcal infection and symptomatic disease in a mammalian host comprising administering an effective amount of a composition according to claim 76.~~

~~78. A kit for diagnosing infection with *N. meningitidis* in a human or animal comprising a component selected from the group consisting of an Omp85 protein of *N. meningitidis*, a fragment thereof, an anti-Omp85 antibody of claim 53, a nucleic acid sequence encoding an Omp85 protein of *N. meningitidis*, and a fragment thereof, and suitable detectable labels.~~

~~79. A method of identifying compounds which specifically bind to Omp85 of *N. meningitidis* or a fragment thereof, comprising the steps of contacting said Omp85 protein of *N. meningitidis* or fragment with a test compound to permit binding of the test compound to Omp85, and determining the amount of test compound which is bound to Omp85.~~

~~80. A compound identified by the method of claim 79.~~

~~81. A method of identifying a pharmacomimetic of Omp85 of *N. gonorrhoeae* or *N. meningitidis* comprising the steps of:~~

~~(a) identifying a compound which binds to Omp85 by screening said Omp85 against a battery of compounds;~~

~~(b) performing computer modelling of the three dimensional structure of said Omp85 or said binding compound of step (a) to identify a compound with the same three dimensional structure as Omp85 or its binding compound; and~~

~~(c) screening said selected compound in a biological assay.~~

1. An immunogenic composition comprising
  - (a) a polypeptide or peptide selected from the group consisting of
    - i. the polypeptide of SEQ ID NO. 2, a homolog thereof, or a fragment thereof of at least eight consecutive amino acids in length, which induces antibodies to *N. gonorrhoeae* in a mammalian subject, and
    - ii. a homolog of SEQ ID NO. 4, or a fragment thereof of at least eight consecutive amino acids in length, which induces antibodies to *N. gonorrhoeae* in a mammalian subject, and
  - (b) a pharmaceutically acceptable carrier
2. The composition according to claim 1, wherein said polypeptide (a) is a sequence that contains one to four conservative amino acid replacements in the amino acid sequence of SEQ ID NO. 2 or 4.
3. The composition according to claim 1, wherein said polypeptide (a) is a homolog having at least 85% identity with the sequence of SEQ ID NO. 2 or 4.
4. The composition according to claim 1, wherein said polypeptide or peptide is fused to a second polypeptide or protein.
5. The composition according to claim 4, wherein said second polypeptide or protein is an antigen or fragment thereof from a heterologous pathogenic species or a homologous pathogenic species.
6. The composition according to claim 1, wherein said fragment comprises an amino acid sequence within amino acids 720 to 745 of SEQ ID NO. 2 or 4.

7 The composition according to claim 1, wherein said fragment comprises an amino acid sequence within amino acids 1 to 178 of SEQ ID NO. 2 or 4.

8 An immunogenic composition comprising:

- (a) a nucleic acid sequence selected from the group consisting of
  - i a nucleic acid sequence of SEQ ID NO. 1, a sequence capable of hybridizing thereto under stringent conditions, or a fragment thereof, which, when expressed in a host cell, produces a polypeptide that induces antibodies to *N. gonorrhoeae*,
  - ii a nucleic acid sequence of SEQ ID NO. 3, a sequence capable of hybridizing thereto under stringent conditions, or a fragment thereof, which, when expressed in a host cell, produces a polypeptide that induces antibodies to *N. meningitidis*, and
- (b) a pharmaceutically acceptable carrier.

9 The composition according to claim 8, wherein said nucleic acid sequence has at least 85% identity with the sequence of SEQ ID NO. 1 or 3.

10 The composition according to claim 8, wherein said nucleic acid sequence encoding said polypeptide is fused to a second nucleic acid sequence encoding a second polypeptide or protein.

12 The composition according to claim 8, further comprising a suitable nucleic acid delivery vehicle.

13 The composition according to claim 10, wherein said second polypeptide is at least one other antigen or fragment thereof from a heterologous pathogenic species or a homologous pathogenic species.

14. The composition according to claim 8, wherein said fragment encodes an amino acid sequence within amino acids 720 to 745 of SEQ ID NO. 2 or 4.

15. The composition according to claim 8, wherein said fragment encodes an amino acid sequence within amino acids 1-178 of SEQ ID NO. 2 or 4.

16. A diagnostic composition comprising at least one component selected from the group consisting of

(a) the polypeptide of SEQ ID NO. 2, a homolog thereof, or a fragment thereof of at least eight consecutive amino acids in length, which induces antibodies to *N. gonorrhoeae* in a mammalian subject;

(b) the polypeptide of SEQ ID NO. 4, a homolog thereof, or a fragment thereof of at least eight consecutive amino acids in length, which induces antibodies to *N. gonorrhoeae* in a mammalian subject;

(c) a nucleic acid sequence of SEQ ID NO. 1, a sequence capable of hybridizing thereto under stringent conditions, or a fragment thereof, which, when expressed in a host cell, produces a polypeptide that induces antibodies to *N. gonorrhoeae*;

(d) a nucleic acid sequence of SEQ ID NO. 3, a sequence capable of hybridizing thereto under stringent conditions, or a fragment thereof, which, when expressed in a host cell, produces a polypeptide that induces antibodies to *N. meningitidis*; and

(e) a polypeptide of (a) or (b) that contains, or a nucleic acid sequence of (c) or (d) that encodes, one to four conservative amino acid replacements in the amino acid sequence of SEQ ID NO. 2 or 4;

(f) a polypeptide of (a) or (b) that contains, or a nucleic acid sequence of (c) or (d) that encodes, a polypeptide that has at least 85% identity with the sequence of SEQ ID NO. 2 or 4;

(g) a polypeptide of (a) or (b) that contains, or a nucleic acid sequence of (c) or (d) that encodes, a second polypeptide or protein;



(h) a polypeptide fragment of (a) or (b) that contains, or a nucleic acid sequence of (c) or (d) that encodes, a peptide fragment that comprises an amino acid sequence within amino acids 720 to 745 of SEQ ID NO 2 or 4;

(i) a polypeptide of (a) or (b) that contains, or a nucleic acid sequence of (c) or (d) that encodes, a peptide fragment that comprises an amino acid sequence within amino acids 1 to 178 of SEQ ID NO 2 or 4, and

a suitable detectable label or detection system associated therewith

17 The compositions according to claim 16, which is a diagnostic reagent

18 The composition according to claim 16, with is a diagnostic kit

18 A nucleic acid molecule comprising (a) a nucleic acid sequence of SEQ ID NO 1, a sequence capable of hybridizing thereto under stringent conditions, or a fragment thereof, which, when expressed in a host cell, produces a polypeptide that induces antibodies to *N. gonorrhoeae*, or (b) a nucleic acid sequence of SEQ ID NO 3, a sequence capable of hybridizing thereto under stringent conditions, or a fragment thereof, which, when expressed in a host cell, produces a polypeptide that induces antibodies to *N. meningitidis*, under the control of suitable regulatory sequences which direct expression of said polypeptide in said host cell

19 A host cell transformed with the molecule of claim 18